GUIDELINES FOR THE MANAGEMENT OF HEPATITIS C

GUIDELINES FOR THE MANAGEMENT OF HEPATITIS C

HEPATITIS, VIRAL

A brief overview of hepatic viruses other than C -

The hepatitis A virus **(HAV)** infection is usually acquired by the fecal-oral route, produces a self-limited disease that does not result in chronic infection or long-term liver disease. It usually produces symptoms of acute viral hepatitis and includes abdominal pain anorexia, dark urine, fever, abnormal enlargement of the liver, jaundice, malaise, nausea, and vomiting. Among adolescents and adults after an average incubation period of 28 days (range: 15 - 50 days). Signs and symptoms usually last <2 months, although 10 - 15% of symptomatic persons have prolonged or relapsing disease lasting <6 months. Peak infectivity occurs during the 2-week period before the onset of jaundice or elevation of liver enzymes, when the concentration of virus in stool is highest. Persons with chronic liver disease who acquire hepatitis A are at increased risk for fulminant hepatitis. A vaccine is available for HAV.

The hepatitis B virus (**HBV**) is a bloodborne pathogen, transmitted by percutaneous or permucosal (e.g., sexual) exposure to infectious blood or body fluids (e.g., semen or saliva).

Acute hepatitis B develops in approximately 30 - 50% of adults at the time of initial infection and is characterized by anorexia, nausea, vomiting, and often jaundice. The risk of progression to chronic infection varies with age, being highest among young children and infants (30 - 90%) and lowest among adolescents and adults (2 - 6%). Persons with chronic HBV infection have a 15 - 25% lifetime risk of death from chronic liver disease or hepatocellular carcinoma (HCC). A vaccine is available to prevent HBV.

The hepatitis D virus **(HDV)** is transmitted when blood or body fluids from an infected person enter the body of a person who is not immune. HDV can only replicate with the help of HBV. HDV infection can be acquired either as a co-infection with HBV or as a superinfection of persons with chronic HBV infection. Persons with HBV-HDV co-infection may have more severe acute disease and a higher risk of fulminant hepatitis (2% - 20%) compared with those infected with HBV alone; however, chronic HBV infection appears to occur less frequently in persons with HBV-HDV co-infection. Chronic HBV carriers who acquire HDV superinfection usually develop chronic HDV infection. In long-term studies of chronic HBV carriers with HDV superinfection, 70% - 80% have developed evidence of chronic liver diseases with cirrhosis compared with 15% - 30% of patients with chronic HBV infection alone.

The hepatitis E virus (**HEV**) is transmitted when the fecal waste of an infected individual orally enters a person who is not immune. The incubation period following exposure to HEV ranges from 15 to 60 days (mean, 40 days). Typical clinical signs and symptoms of acute hepatitis E are similar to those of other types of viral hepatitis and include abdominal pain anorexia, dark urine, fever, abnormal enlargement of the liver, jaundice, malaise, nausea, and vomiting. Other less common symptoms include joint pain, diarrhea, itching, and urticarial rash. The period of infectivity following acute infection has not been determined but virus excretion in stools has been demonstrated up to 14 days after illness onset. No evidence of chronic infection has been detected in long-term follow-up of patients with hepatitis E. HEV is rarely found in the United States. Persons primarily at risk for HEV are travelers to areas with HEV outbreaks. Persons traveling to these regions should be advised to avoid the local tap water and practice good hygiene and sanitation. HEV usually resolves on its own over several weeks or months. No vaccine is available for HEV.

Some cases of viral hepatitis cannot be attributed to the hepatitis A, B, C, D, or E viruses. These are called non-A...E hepatitis, or hepatitis X. Scientists have identified several candidate viruses, but none have been proven to cause hepatitis. The search for the virus responsible for hepatitis X is continuing.

Type C (HCV) (acute)

Disease and Epidemiology:

Etiologic Agent -

The etiologic agent of hepatitis C **(HCV)** is a flavivirus (same family as the yellow fever virus). It is unrelated to the viruses that cause hepatitis A (HAV) or hepatitis B (HBV). The virus was not officially identified until 1990 when a specific test that identified it was developed. Prior to that time it was referred to as non-A, non-B hepatitis.

Clinical Description -

Sixty to seventy percent of HCV infected individuals have no noticeable symptoms. Jaundice (yellowing of skin and whites of the eyes) may be present in 20-30% of HCV infected individuals, while another 10-20% may exhibit non-specific symptoms (e.g., anorexia, malaise, or abdominal pain). When symptoms are present, the average time period after exposure is 6-7 weeks. The average time period from exposure to seroconversion is 8-9 weeks. Twenty to forty percent of **acute** viral hepatitis in the U.S. may be caused by HCV; however, the number of reported cases is considerably smaller.

The most common feature of acute HCV infection is elevated serum alanine aminotransferase levels (ALT), usually in a fluctuating pattern.

Reservoirs -

Humans.

Modes of Transmission -

HCV transmission occurs primarily through exposure to infected blood. This exposure exists in the context of illegal injection drug use, blood transfusions before 1992, solid organ transplantation from infected donors, unsafe medical practices, occupational exposure to infected blood, birth from an infected mother, and high-risk sexual practices, (especially multiple sex partners). Body piercing, tattooing (especially if done in non-commercial settings), and intranasal cocaine use could also be methods of transmission. Transmission from blood products and organ transplants was virtually eliminated by the introduction of a more sensitive test for HCV antibodies in mid-1992.

Incubation Period -

The incubation period for HCV ranges from 2 – 26 weeks, with an average of 6 – 7 weeks.

Infectious Period -

How long an infected person remains infectious to others has yet to be determined, therefore, anyone who tests positive for the virus should be considered infectious. The correlation between the quantity of circulating virus (viral load) and infectiousness is not clearly defined. Viremia is probably low, relative to hepatitis B and high, relative to HIV.

Epidemiology -

About 15 - 20 % of individuals infected with acute HCV will spontaneously clear the virus. The reasons for this are not known but are being researched.

HCV infection is found in persons of all ages, though the highest incidence of *acute* HCV is in the 20 to 39 year age group, and males predominate. Persons of Hispanic ethnicity have the highest incidence of *acute* infection, while African Americans and Caucasians have similar incidence rates.

High HCV seroprevalence rates (from 15 to 50 percent) have occurred in specific subpopulations, such as the homeless, incarcerated persons, injection drug users, and persons with hemophilia who were treated with clotting factors before 1992. The highest seroprevalence rates (70 percent to more than 90 percent) have been reported in the last two groups.

Current estimates of annual newly acquired infections of HCV are 35,000. Indiana reported no cases of acute HCV for 2001.

Case Definition (Acute HCV):

Clinical Description -

An acute illness with

- discrete onset of symptoms consistent with acute viral hepatitis, and
- jaundice or elevated serum aminotransferase levels (ALT)

Laboratory criteria -

- Serum aminotransferase levels >7 times the upper limit of normal, and
- IgM anti-HAV negative, and
- IgM anti-HBc negative (if done) or HBsAg negative and

Or

Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. recombinant immunoblot strip assay [RIBA] for anti-HCV or RT-PCR for HCV RNA [Test to detect HCV RNA by amplification of viral genetic sequences]

Or

Anti-HCV positive by RIBA alone

Or

HCV RNA positive

Case classification -

Confirmed: A case that meets the clinical case definition and is laboratory confirmed.

NOTE: If an initial EIA is shown to be positive but did not meet the s/c of 3.8 and a supplementary test is negative, the original EIA anti-HCV was **false positive**.

Comment:

- 1. Up to 10% of cases of acute hepatitis C will be anti-HCV negative when tested initially because some have not yet seroconverted and others (<3%) remain negative even with prolonged follow up.
- 2. Available serologic tests for anti-HCV do not distinguish between acute and chronic or past infection. Thus, other causes of acute hepatitis should be excluded for anti-HCV positive individuals who have an acute illness compatible with hepatitis.
- Detecting HCV RNA using gene amplification techniques (e.g. RT-PCR) can make the diagnosis of HCV infection. However, a negative HCV RNA test result <u>does not</u> exclude the possibility of HCV infection.

HEPATITIS, VIRAL, TYPE C (CHRONIC)

Epidemiology-

HCV is the most common chronic blood-borne infection the in United States. Estimates are at least 3.9 million (1.8%) Americans have been infected with HCV. Of those, approximately 2.7 million have developed chronic infection. Forty to sixty percent of chronic liver disease is HCV-related with 8,000-10,000 deaths occurring each year. Indiana received 5,512 reports of individuals testing positive for HCV infection in 2001.

In the general population, the highest rates of chronic HCV infection are found among persons aged 30 to 49 years, with males again in the majority. Unlike the ethnic pattern of *acute* disease, African Americans have a substantially higher incidence of chronic HCV infection than do Caucasians.

Factors that appear to promote disease progression or severity are amount of alcohol intake after infection; being older than 40 at time of infection; having co-infections such as HIV or HBV; and male gender.

Case Definition (Chronic HCV):

Clinical Description -

The course of chronic liver disease is usually insidious, progressing at a slow rate without symptoms or physical signs in the majority of individuals during the first two or more decades after infection.

Laboratory criteria -

 Hepatitis C Virus Antibody (Anti-HCV) positive (repeat reactive)by an enzyme immunoassay (EIA) with a signal to cut-off ratio of ≥ 3.8

Or

 Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or RT-PCR for HCV RNA)

Or

Anti-HCV positive by RIBA alone

Or

HCV RNA positive

Case Classification -

Confirmed: A case that is laboratory confirmed and does not meet the case definition for *acute* hepatitis C.

Probable: A case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotranferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.ⁱⁱⁱ

NOTE: If an initial EIA is shown to be positive but did not meet the s/c of 3.8 and a supplementary test is negative, the original EIA anti-HCV was *false positive*.

PERINATAL HEPATITIS C

Rate of Infection -

The rate of HCV infection among infants born to mothers who are only infected with HCV is 5-6%. If the mother is infected with both HCV and HIV, the rate of infection increases to 14-17%.

Delivery Mode and Breastfeeding Relationship -

Data regarding the relationship between delivery mode and HCV transmission are limited and presently indicate no difference in infection rates between infants delivered vaginally compared with cesarean-delivered infants.

The transmission of HCV infection through breast milk has not been documented. In the studies that have evaluated breastfeeding in infants born to HCV-infected women, the average rate of infection was 4% in both breastfed and bottle-fed infants. Therefore, breastfeeding is not contraindicated in HCV-positive mothers.

Recommendations for follow up -

Infants born to infected mothers should be screened for HCV. Because of the presence of maternal antibodies, children younger than twelve (12) months should only be tested by HCV RNA methods, but children over twelve months can be tested using the anti-HCV EIA test. Children positive for either anti-HCV or HCV RNA should be evaluated for the presence or development of liver disease, and children with persistently abnormal ALT's should be referred to a specialist for medical management.

POST EXPOSURE

Available data regarding the prevention of HCV infection with immune globulin (IG) indicate that IG is not effective for post-exposure prophylaxis of HCV. No assessments have been made of post-exposure use of antiviral agents (e.g., interferon) to prevent HCV infection. Interferon is not FDA approved or recommended at this time for a prophylactic treatment to HCV exposure.

PUBLIC HEALTH SIGNIFICANCE

Current estimates of medical and work-loss costs of HCV-related acute and chronic liver disease are >\$600 million annually. HCV- associated end-stage liver disease is the most frequent indication for liver transplantation among adults.

Due to the length of time (10-20~years) that it normally takes for liver damage to occur, individuals are typically in their forties or fifties when serious complications arise. This also coincides with the peak income producing time frame for most individuals. Many infected individuals who develop chronic liver disease are then forced to rely on public assistance because of an inability to work.

ROLE OF LOCAL HEALTH DEPARTMENTS

DISEASE REPORTING:

Purpose of Surveillance and Reporting-

- To provide a reliable database that can be used to direct prevention and control efforts
- To evaluate impact of prevention and control activities
- To measure overall burden of disease within a jurisdiction
- To monitor trends in incidence of and risk factors for disease
- To Identify infected persons requiring counseling and medical follow up
- To identify contacts of infected persons requiring counseling
- To target provider education efforts

Physician and Hospital Administrator Reporting Requirements -

Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories 410 IAC 1-2.3 (Effective October 11, 2000)

Sec. 47.

- (a) It shall be the duty of each physician licensed under IC 25-22.4, and each administrator of a hospital licensed under IC 16-21, or the administrator's representative, to report all cases, and suspected cases of the diseases listed in subsection (d)* Reporting of specimen results by a laboratory to health officials does not nullify the physician's or administrator's obligations to report said case.
- (b) The report required by subsection (a) shall be made to the local health officer in whose jurisdiction the patient was examined at the time the diagnosis was made or suspected.

Thus, physicians and hospitals are only required to report acute cases of HCV.

^{*}Subsection D includes Hepatitis, viral, Type C (acute). Report within 72 hours.

Laboratory Reporting Requirements -

Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories 410 IAC 1-2.3 (Effective October 11, 2000)

Sec. 48.

- (a) Each director, or the director's representative, of a medical laboratory in which examination of any specimen derived from the human body yields microscopic, bacteriologic, immunologic, serologic, or other evidence of infection by any of the organisms or agents listed in section 48 (d)* of this rule shall report such findings and any other epidemiologically necessary information requested by the Indiana State Department of Health.
- (b) The report required by subsection (a) shall, at a **minimum**, include the following:
 - (1) Name, date, results of test performed, the laboratory's normal limits for that test, and the laboratory's interpretation of the test results.
 - (2) Name of person and date of birth or age from whom specimen was obtained.
 - (3) Name, address, and telephone number of attending physician, hospital, clinic, or other specimen submitter.
 - (4) Name, address and telephone number of the laboratory performing the test.
- (c) This subsection does not preclude laboratories from testing specimens, which, when submitted to the laboratory, are identified by a numeric identifier code and not by name of patient. If testing of such a specimen, identified by a numeric identifier code, produces results that are required to be reported under this rule, the laboratory shall submit a report that includes the following:
 - (1) Numeric identifier code, date, and results of tests performed.
 - (2) Name and address of attending physician, hospital, clinic, or other.
 - (3) Name and address of the laboratory performing the test.

*Subsection d includes laboratory findings demonstrating evidence of the following infections, diseases, or conditions shall be reported at least weekly to the Indiana State Department of Health:

(26) Hepatitis viruses:

(C) RIBA or RNA or Anti-HCV, or any combination.

Thus, laboratories are required to report positive anti-HCV, RIBA's, and HCV RNA's but the demographic information may be limited to that with which the laboratory is provided.

Local Health Department Responsibility -

Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories 410 IAC 1-2.3 (Effective October 11, 2000)

Sec. 49.

- (a) Case reports submitted to the local health department or the Indiana State Department of Health may be used for epidemiological investigation or other disease intervention activities as warranted.
- (b) Unless otherwise indicated, the local health department in the jurisdiction where the patient is a resident is responsible for performing any epidemiological investigation required and instituting control measures.
- (c) Upon receiving a communicable disease report of *acute* HCV, local health officers must investigate the report not more that seventy-two (72) hours after the report is received for other diseases.

- (d) Investigation shall include obtaining laboratory and clinical data necessary for case ascertainment. Investigation efforts should identify all potential means for disease acquisition, risk factors, and any potential public health threats posed by the case. Findings of the investigation shall be used to institute control measures to minimize or abrogate the risk of disease spread.
- (e) The results of the investigation shall be documented, in writing, with a copy maintained at the local health department, and a copy forwarded to the Indiana State Department of Health's communicable disease section.

Sec. 74. Hepatitis C

The specific control measures for HCV (acute) are as follows:

- (1) An investigation shall be performed within seventy-two (72) hours by the local health department officer for the purpose of determining risk factors for infection.
- (2) Standard precautions for hospitalized patients and universal precautions for others, where exposure to blood or other potentially infectious materials or both is a possibility.

Infected persons shall not:

- (A) share needles or syringes with other persons;
- (B) donate blood, plasma, or organ transplantation; or
- (C) donate semen for artificial insemination.
- (3) Equipment contaminated with blood or other infectious body materials or both, shall be appropriately disinfected or sterilized prior to reuse.
- (4) Quarantine is not required.
- (5) HCV-positive individuals shall not share razors or toothbrushes with others. Health care workers with percutaneous or permucosal exposure to HCV shall have baseline and six (6) month follow up serologic testing for anti-HCV and alanine aminotransferase activity. There are no restrictions to working in the health care field for anyone found to be positive with the hepatitis C virus.

REPORTS SENT TO THE LOCAL HEALTH DEPARTMENT

Local Health Departments (LHD) are requested to forward <u>all</u> laboratory reportable HCV test results to the Indiana State Department of Health. This would include test results for both acute and chronically ill persons. If additional follow up is indicated, the laboratory report should be attached and forwarded along with the appropriate completed forms.

Follow up with the infected individual is currently required only for acute cases. Since the majority of acute HCV cases occur in individuals under 40 years age, the Indiana State Department of Health recommends follow up with the health care provider of all reports on any person who falls within this age range to determine if this a newly acquired infection.

Health departments that have the capability of following up on all HCV reports are encouraged to do so. LHD's that decide to contact HCV-positive individuals for the purpose of disseminating educational messages can refer to the Indiana State Department of Health's web site at www.in.gov/isdh for informational materials.

What to do with positive HCV reports on under 40 year olds from:

A LABORATORY, HEALTH CARE PROVIDER, OR HOSPITAL -

- Contact the health care provider to determine acute or chronic status
- Complete State Form 51031 Determination of Hepatitis C Status found in Appendix A
- Complete State Form 51032 ACUTE and CHRONIC HEPATITIS C WORKSHEET found in Appendix A
- Mail completed forms and laboratory tests to:

Indiana State Department of Health Attn: Hepatitis C Coordinator 2 N. Meridian Street Indianapolis, IN 46204-3003

OR

 FAX to: HCV Coordinator 317-233-7663

NOTE: Laboratory reports received by the Indiana State Department of Health on individuals under 40 will be referred to the individual's LHD if known. Otherwise, it will be sent to the LHD of the submitting health care provider's county of practice for follow-up investigative work. If it is determined that the individual is an acute case of HCV and resides in a different LHD's jurisdiction, information should be forwarded to the correct LHD for follow up with the infected individual.

What to do with positive HCV reports individuals 40 and over from:

A LABORATORY-

Send to the Indiana State Department of Health

A HEALTH CARE PROVIDER OR HOSPITAL -

- If individual has a symptom consistent with hepatitis C, follow the same procedure as for those under 40.
- If individual is asymptomatic, send to the Indiana State Department of Health.
- Complete State Form 51031 Determination of Hepatitis C Status found in Appendix A

HOW TO COMPLETE:

STATE FORM 51031-DETERMINATION OF HEPATITIS C STATUS -

Appendix A provides STATE FORM 51031 and STATE FORM 51032.

- Contact the diagnosing health care provider to verify the diagnosis and obtain the information necessary to complete State Form 51031.
- If the individual meets the case definition of an **acute** case of HCV, inform the health care provider that you will need to contact the person to perform additional disease investigation.
- Find out if the health care provider has notified the person of their test results and what type of follow-up information has been provided to the patient.

- State Form 51031 is a telescan form. It is therefore very important that the information be
 recorded accurately and neatly, placing only one number or capital letter per box and
 completely filling in circles so that the machines can accurately read the information.
- If you have made several attempts to obtain case information, but have been unsuccessful (e.g., the health care provider does not return your calls or respond to a letter), please fill out the form with as much information as you have gathered. Please note on the form the reason it could not be completely filled out.

Appendix B provides a sample health care provider letter and questionnaire.

STATE FORM 51032- HEPATITIS C WORKSHEET -

NOTE: THIS FORM SHOULD BE COMPLETED IN ACUTE CASES **AND** CASES UNDER 40 YEARS OLD.

FOR ACUTE CASES

- Once it is determined that the individual is an **acute** case of HCV attempt to contact the person.
- Some questions on the report form are quite personal and should be asked in a sensitive way.
- Reassure individuals that all information being requested is strictly confidential. For all
 risk-related questions on the report form, it is essential that the investigator <u>not assume</u> the
 person's risk. Get the information concretely from the individual, their medical provider(s) or
 indicate that the risk is unknown for this case. Other than obtaining the information and
 providing related health education, the LHD does not have further responsibility in relation to
 this information.
- State Form 51032 is a telescan form. It is therefore very important that the information be
 recorded accurately and neatly, placing only one number or capital letter per box and
 completely filling in circles so that the machines can accurately read the information.

Appendix C provides sample letters for contacting individuals with a positive HCV report.

FOR CASES UNDER 40 YEARS OLD

- Contact the diagnosing health care provider to verify the diagnosis and obtain the information necessary to complete **State Form 51031 and State Form 51032**.
- If the healthcare provider does not have the information necessary to complete **State Form 51032** then attempt to contact the person.
- Reassure individuals that all information being requested is strictly confidential. For all risk-related questions on the report form, it is essential that the investigator <u>not assume</u> the person's risk. Get the information concretely from the individual, their medical provider(s) or indicate that the risk is unknown for this case. Other than obtaining the information and providing related health education, the LHD does not have further responsibility in relation to this information.
- State Form **51032** is a telescan form. It is therefore very important that the information be recorded accurately and neatly, placing only one number or capital letter per box and completely filling in circles so that the machines can accurately read the information.

Appendix C provides sample letters for contacting individuals with a positive HCV report.

Appendix D provides a sample of epidemiology progress notes that can be used by the LHD. These notes are for LHD use only and **do not** need to be submitted to the Indiana State Department of Health.

INVESTIGATIVE SUMMARY

ACUTE CASES

- COMPLETE STATE FORM 51031 Determination of Hepatitis C Status
- COMPLETE STATE FORM 51032 –HEPATITIS C WORKSHEET
- ATTACH ALL LABORATORY REPORTS
- MAIL COMPLETED FORMS AND LABORATORY REPORTS TO:

Indiana State Department of Health Attn: Hepatitis C Coordinator 2 N. Meridian Street Indianapolis, IN 46204-3003

OR

FAX to: HCV Coordinator

317-233-7663

CHRONIC CASES under 40 years old

- COMPLETE STATE FORM 51031 Determination of Hepatitis C Status
- COMPLETE STATE FORM 51032 –HEPATITIS C WORKSHEET
- ATTACH ALL LABORATORY REPORTS
- MAIL COMPLETED FORMS AND LABORATORY REPORTS TO:

Indiana State Department of Health Attn: Hepatitis C Coordinator 2 N. Meridian Street Indianapolis, IN 46204-3003

OR

FAX to: HCV Coordinator

317-233-7663

CHRONIC CASES 40 and over

- COMPLETE STATE FORM 51031 Determination of Hepatitis C Status
- ATTACH ALL LABORATORY REPORTS

MAIL COMPLETED FORMS AND LABORATORY REPORTS TO:

Indiana State Department of Health Attn: Hepatitis C Coordinator 2 N. Meridian Street Indianapolis, IN 46204-3003

OR

• FAX to: HCV Coordinator

317-233-7663

CONTROL MEASURES

Institution of disease control measures is an integral part of case investigation. The following information is provided to assist LHD's in determining what type of measures need to be implemented in their community.

Patient Information -

HCV-infected individuals are prohibited by law from sharing needles or syringes with other persons, donating blood, plasma, or organs for transplantation, or donating semen for artificial insemination. Equipment contaminated with blood or other infectious body materials or both, shall be appropriately disinfected or sterilized prior to reuse. Quarantine is not required. Individuals are discouraged from sharing razors, toothbrushes or any other personal items that may come in contact with their blood.

Note: Sexual transmission of HCV is estimated to occur in 15% of cases, with more efficient transmission occurring from male to female, than male to male or female to male. Because this virus is transmitted during blood to blood contact, females should abstain from sexual activity or use sexual barrier protection during their menstrual cycle.

Protection of Individuals exposed to HCV infected blood -

Use of universal precautions is required to prevent exposing others to blood and body fluids. IG prophylaxis is not effective and is not recommended for contacts of HCV-infected individuals; however, all persons coming in contact with blood and/or body fluids of an HCV- infected person are strongly encouraged to be tested for HCV. The Indiana State Department of Health will provide testing for HCV upon request by the LHD.

Casual Contact and Work Setting Information -

There are no specific regulations regarding HCV infection for food handlers, in day care, school or community residential programs. HCV is not spread via casual contact or through food or water. As long as universal precautions are maintained, HCV will not be spread to others in these settings. No one who is HCV-infected should be excluded from attending or working in any of these settings on the basis of their HCV infection.

SPECIAL CIRCUMSTANCES

If the LHD receives a request from any health care provider to notify an individual of a positive HCV report, the LHD may consider complying with this request. However, it should be stressed to the requesting party that under the standard of care practice it is customary for the health care provider to give this information.

ADDITIONAL INFORMATION

Appendix E provides web site links for additional information on HCV.

FOOTNOTES

ⁱ (The ratio of reported acute cases to the total number of newly acquired infections occurring was estimated by catalytic modeling of seroprevalence data (from the National Health and Nutrition Examination Survey (NHANES III)). Incidence estimates adjusted for underreporting and asymptomatic infections were then calculated by multiplying the number of cases reported (for hepatitis C, Sentinel Counties Study of Viral Hepatitis data are used) by these ratios.

ⁱⁱThis case definition was approved by CSTE in June 2000. It has been updated from the previously published case definition

 $^{^{\}rm iii}{\rm This}$ case definition was approved by CSTE in October 2002.

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Chin, J., ed. *Control of Communicable Diseases Manual, 17th Edition.* Washington, DC, American Public Health Association, 2000.

Indiana State Department of Health, *Communicable Disease reporting Rule for Physicians, Hospitals, and Laboratories*. Effective October 11, 2000.

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Appendix

A

Determination of Hepatitis C Status - Page 1 of 2

Indiana State Department of Health State Form 51031 (9-02)

| DIRECTIONS - PLEASE READ BEFORE YOU BEGIN: | | | | |
|--|------------------------------|---|--|--|
| 1 Print firmly and neatly. 3 Fill-in circles like this: • 4 Print capital letters only 5 Please complete | | | | |
| 2 Only use pens with blue or | ~ ~ | d numbers completely A 2 C 3 all items on form. Date format: | | |
| black ink. | Mark mistakes like this: ins | ide boxes. MM/DD/YY | | |
| Leave Blank for State & Authorized Health Department Use ○ Confirmed Acute HCV Use this form to report | | | | |
| Report O Confirmed HCV Status: O Suspect HCV Ir | | Acute Hepatitis C | | |
| O Revoked | | | | |
| | Section 1: Demographi | c Information | | |
| Last Name | | | | |
| First Name | | MI Phone Number | | |
| | | | | |
| Number & Street Address | | | | |
| | | | | |
| City | | State Zip Code | | |
| | | | | |
| County | Date of Bi | rth Sex | | |
| | | / / O Male O Female O Unknown | | |
| Age Comparison Race: Comparison Com | | | | |
| Date of Diagnosis: Did this patient have any symptoms at the time of diagnosis? O Yes O No O Unk | | | | |
| If yes, date of the first symptor | ms: | Was the patient jaundiced? ○ Yes ○ No ○ Unk | | |
| Was the patient hospitalized? | O Yes O No O Unk | Did the patient die from Hepatitis? O Yes O No O Unk | | |
| | Section 3: Clinica | al Data | | |
| Attach a copy of all laboratory results | | | | |
| Laboratory Results: | | | | |
| Test | Result | <u>Date</u> | | |
| Anti-HCV screening antibody (e.g. ELISA, EIA) | O Positive O Negative O | Unk// | | |
| Anti-HCV supplementary test (e.g. RIBA) | O Positive O Negative O | Pending O Ind O Unk / / / / | | |
| Viral RNA (e.g. PCR) | O Positive O Negative O | Pending O Unk | | |

Determination of Hepatitis C Status - Page 2 of 2

Indiana State Department of Health State Form 51031 (9-02)

Section 3: Clinical Data (continued)

If an acute case:

Note: This form is only for reporting Acute HCV. Use separate forms for HAV and HBV. Chronic HCV is not required to be reported by hospitals and physicians.

| hospitals and physicians. | | | |
|---|----------------|------------------------|-------------|
| <u>Test</u> | | Result | <u>Date</u> |
| IgM hepatitis A antibody (IgM anti-HAV) | O Positive | O Negative | O Unk / / |
| Total hepatitis A antibody (Total anti-HAV) | O Positive | O Negative | O Unk / / / |
| IgM hepatitis B core antibody (IgM anti-HBo | C) O Positive | O Negative | O Unk / / / |
| Hepatitis B surface antigen (HBsAg) | O Positive | O Negative | O Unk / / / |
| ALT (SGPT) Results | AST (SGOT) R | esults | |
| Sec | ction 4: Comme | ents/Provider Informat | ion |
| Comments: | | | |
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| | | | |
| Investigator Name | | | |
| | | | |
| Agency | | | |
| Phone Number | | Date | |
| | | | |

ACUTE and CHRONIC HEPATITIS C WORKSHEET - Page 1 of 2

Indiana State Department of Health State Form 51032 (9-02)

| DIRECTIONS - PLEASE READ BEFORE YOU BEGIN: | | | | | |
|---|---|-----------------------------|----------------|--------------|--|
| 1 Print firmly and neatly. 3 Fill-in circles like this: • 4 Print firmly and neatly. | nt capital letters only | | | | |
| | d numbers completely A 2 C 3 all items on form. • Date format: | | | | |
| black ink. Mark mistakes like this: inside | de boxes. | | | M/DD/YY | |
| | | | | | |
| CONFIDENTIAL: For Public Health Use Only, File with Source Cas Hepatitis C worksheet for medical, drug/ alcohol and sexual histor | | tion of Hepatitis C s | status form. (| Complete the | |
| Case Name: | , | D | ate of Birth | | |
| | | | | | |
| | | | / | / | |
| Case Risk History - Ch | neck all that a | pply | | | |
| Medical History | Yes, in last 6 months | Yes, more than 6 months ago | No | Unknown | |
| Did the patient receive blood or blood products (transfusion)? | 0 | 0 | 0 | 0 | |
| If yes, specify dates(s): From / / / | То |]/ | | | |
| Did the patient receive care in a dialysis or kidney transplant uni | it? (| 0 | 0 | 0 | |
| Was the patient employed in a medical, dental, or other field involving contact with human blood or other bodily fluids? | 0 | 0 | 0 | 0 | |
| Did the patient have dental surgery? | 0 | 0 | 0 | 0 | |
| Did the patient have other surgery? | 0 | 0 | 0 | 0 | |
| Did the patient have an accidental stick/puncture with a contaminated needle/sharp object? | 0 | 0 | 0 | 0 | |
| Did the patient have other exposure to someone else's blood? | 0 | 0 | 0 | 0 | |
| If yes, specify: | | | | | |
| | | | | | |
| Drug/Alcohol History | Yes, in last | Yes, more than | No | Unknown | |
| <u> </u> | 6 months | 6 months ago | _ | _ | |
| Did the patient use needles for injection of street drugs? | 0 | 0 | 0 | 0 | |
| Did the patient use intranasal street drugs? | 0 | 0 | 0 | 0 | |
| Did the patient use alcohol? | 0 | 0 | 0 | 0 | |
| Was the patient ever admitted to any drug treatment program? | 0 | 0 | 0 | 0 | |
| Please ask all the following questions regardless of the case's gender. | | | | | |
| Sexual History | Yes, in last 6 months | Yes, more than 6 months ago | No | Unknown | |
| Was the patient a sexual contact of a confirmed or suspected HCV case? | 0 | 0 | 0 | 0 | |
| How many different male sexual partners has the patient had: | None 1 | 2 - 5 | 5 - 10 >10 | Unknown | |
| In the last 6 months? Ever (in their lifetime)? | 0 0 | | 0 0 | | |
| How many different female sexual partners has the patient had: | | | | | |
| In the last 6 months? Ever (in their lifetime)? | 0 0 | | 0 0 | | |

ACUTE and CHRONIC HEPATITIS C WORKSHEET - Page 2 of 2

Indiana State Department of Health State Form 51032 (9-02)

| Case Risk History - Check all that apply (continued) | | | | |
|--|--------------------------|--------------------------------|----|---------|
| Other Risk History | Yes, in last 6 months | Yes, more than 6 months ago | No | Unknown |
| Was the patient a household (non-sexual) contact of a confirmed or suspected Hepatitis C case? | 0 | 0 | 0 | 0 |
| Did the patient receive a body piercing? | 0 | 0 | 0 | 0 |
| If yes, where was the piercing performed? O Commercial parlor/shop O Correctional Facility | Other, specify: | | | |
| Did the patient receive a tattoo? | 0 | 0 | 0 | 0 |
| If yes, where was the tattooing performed? O Commercial parlor/shop O Correctional Facility | O Other, specify: | | | |
| Cor | nments/Follow-Up | | | |
| Comments: | · | | | |
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| Investigator Name | | | | |
| | | | | |
| Agency | | | • | |
| | | | | |
| Phone Number | Date | | | |
| | | / | | |
| | | // | | |

Appendix

В

Sample Letter For Contacting Health Care Providers For Hepatitis C Case Investigation (Print on LHD Letterhead)

| Dat | Date | | |
|-------------------|--|--|---|
| Dea | Dear | _ | |
| The | Гhe | Health Department | received the attached report regarding the |
| TOIL | following person: | | |
| Pei | Person's Name: Last | First | Date of Birth |
| req lab rec | The revised Reporting Rule for Hospitals, Phy requires health care providers to report acute aboratories are required to report positive HO recombinant immunoblot assay (RIBA), HCV positive tests. | cases of hepatitis (CV test results. The | C virus infection (HCV) only, while tests that must be reported are as follows: |
| | The health care provider's report of acute illnodentified in Indiana. | ess is the only way | in which newly infected persons will be |
| The | The CDC currently defines an acute case of h | nepatitis C as follow | vs: |
| Cli | Clinic criteria | | |
| An • • | | | titis, and |
| Lal | <u>aboratory criteria</u> | | |
| • | IgM anti-HAV negative, and IgM anti-HBc negative (if done) or HBs/ Hepatitis C Virus Antibody (Anti-HCV) p cutoff ratio of 3.8 | Ag negative and | normal, and ge enzyme immunoassay (EIA) signal to |
| | Or | | |
| • | Anti-HCV positive (repeat reactive) by EI recombinant immunoblot strip assay [RIE | | |
| | Or | | |
| • | Anti-HCV positive by RIBA alone | | |
| | Or | | |
| • | HCV RNA positive | | |
| ret De | need your help to determine whether this ca return the following page. Please do not see Department of Health and the CDC encourage with chronic HCV. | end copies of the inc | dividual's chart. Both the Indiana State |

Please note that all information is confidential. Thank you for your help.

Sincerely,

LHD Letterhead

Please complete and return via **FAX** or mail.

| Doctor: Pr | | Phone:() | | |
|-----------------------------|---------------------------------|-----------------------|---------------------|--------|
| Address: | | FAX: () | | |
| Patient's Name: Last | Fir | st | Date of Birth_ | |
| | County of Residence: | | | |
| | Dia | gnosis | | |
| | Acute HCV | OR Chronic HC | CV | |
| Has the patient been cou | nseled about his/her diseas | e? | YES | NO. |
| Are you following the pati | ent for hepatitis C? | | YES | NO. |
| If no, has the patient been | n referred to another M.D. f | or follow-up? | YES | NO. |
| If yes, Dr.'s Name: | | PI | none: () | |
| Address | | | | |
| | If <u>Acute</u> diagnosis made, | please complete the t | following | |
| Symptoms | | _ | onset date// | |
| Jaundice or elevated seru | um aminotransrerase levels | onset dat | te//_ | |
| Serum aminotransferase | levels (must be > 7 times | the upper limit to me | et acute case defin | ition) |
| | AST | ALT | | |
| IgM Anti-HAV | Neg | Pos | Not tested | _ |
| IgM Anti-HBc | Neg | Pos | Not tested | _ |
| HBsAg | Neg | Pos | Not tested | _ |
| Anti-HCV (RIBA) | Neg | Pos | Not tested | _ |
| RT-PCR for HCV RNA | Neg | Pos | Not tested | _ |

Appendix

 C

Sample Letter Of Contacting Patients For Acute Hepatitis C Investigation (Print on LHD Letterhead)

| Date |
|---|
| Patient Name Address City, State, Zip |
| Dear |
| I urgently need to speak with you regarding a diagnosis of acute hepatitis C received from your health care provider. Acute hepatitis C is a disease reportable, by state law, to the Centers for Disease Control and Prevention and to both local and state health departments. Please be advised that this report is strictly confidential and is being followed up to provide you information about how to prevent further spread of this disease. |
| It is very important that you continue follow-up with your doctor in order to be evaluated further for this disease. Hepatitis C can cause serious liver damage in some people, <i>even if they feel fine</i> . It is also important that your household and sexual contacts be protected against this disease. |
| I need to speak with you at your earliest convenience to further discuss this diagnosis. I can be reached at () |
| Sincerely |

Sample Letter For Contacting Individuals Regarding Chronic Hepatitis C (Print on LHD Letterhead)

| Date |
|--|
| Patient Name Address City, State, Zip |
| Dear |
| This letter is being sent as a follow up for laboratory tests performed on blood work you recently had done. The lab report states that your blood tested positive for Hepatitis C, a disease reportable by state law, to the Centers for Disease Control and Prevention and to local and state health departments. Please be advised that this report is strictly confidential and is being followed up to provide information about how to prevent further spread of this disease. It is also important that your household and sexual contacts be protected against this disease. |
| It is very important that you continue follow up with your doctor in order to be evaluated further for this disease. Hepatitis C can cause serious liver damage in some people, even if they feel fine. |
| I need to speak with you at your earliest convenience to further discuss this diagnosis. I can be reached at () |
| Sincerely, |
| |
| |

NOTE: May be used by LHD's choosing to provide education to persons with chronic HCV.

Sample Letter of Contacting Patients from Hepatitis C Blood Bank Reports Investigation (Print on LHD Letterhead)

| Date |
|---|
| Patient Name Address City, State, Zip |
| Dear |
| This letter is being sent to notify you that tests performed on blood you recently donated indicate a positive result for hepatitis C. Hepatitis C is a disease reportable by state law, to the Centers for Disease Control and Prevention and to both local and state health departments. Please be advised that this report is strictly confidential and is being followed up to provide information about how to prevent further spread of this disease. |
| It is very important that you continue follow up with your doctor in order to be evaluated further for this disease. Hepatitis C can cause serious liver damage in some people, <i>even if they feel fine</i> . It is also important that your household and sexual contacts be protected against this disease. |
| I need to speak with you at your earliest convenience to further discuss this diagnosis. I can be reached at () |
| Sincerely |

Appendix

EPIDEMIOLOGY PROGRESS NOTES

| Date Receiv | /ed | Fron | n |
|------------------------------------|-------------------------|------|-----------|
| Patient Name | | | Diagnosis |
| Phone () | | | FAX () |
| Patient Contacted: | 1 st Attempt | Date | Notes: |
| Phone Letter Quick Facts Follow Up | | | |
| Patient Contacted: | 2 nd Attempt | Date | Notes: |
| Phone Letter Quick Facts Follow Up | | | |
| Dr. Name | | | Phone () |
| Address | | | FAX () |
| Doctor Contacted: | 1 st Attempt | Date | Notes: |
| Phone Letter Quick Facts Follow Up | | | |
| Doctor Contacted: | 2 nd Attempt | Date | Notes: |
| Phone Letter Quick Facts Follow Up | | | |
| Date Sent To ISDH: | | | |
| Date Data Entered: | | | |

Appendix

Links to Statistical Charts and Graphs

Reported Cases of Acute Hepatitis C by Selected Risk Factors – United States 1983-1996 <a href="http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hepatitis/slide

Estimated Incidence of Acute HCV Infection United States, 1960-1999

http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_c/slide 7.htm

Serologic Pattern of Acute HCV Infection with Recovery

http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep c/slide 4.htm

Serologic Pattern of Acute HCV Infection with Progression to chronic Infection

http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_c/slide 5.htm

Prevalence of Hepatitis C Virus (HCV) Infection by age and race/ethnicity – United States, 1988-1994

http://www.cdc.gov/ncidod/diseases/hepatitis/C Training/edu/1/default.htm

Prevalence of HCV Infection by Age and Gender, United States, 1988-1994

http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_c/slide_9.htm

Sources of Infection for Persons with Hepatitis C

http://www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep c/slide 12.htm

Chronic Hepatitis C: Current Disease Management

http://www.niddk.nih.gov/health/digest/pubs/chrnhepc/chrnhepc.htm

Viral Hepatitis A to E and Beyond

http://www.niddk.nih.gov/health/digest/pubs/hep/hepa-e/hepa-e.htm#ocvh

Communicable Disease Reporting Rule for Physicians, Hospitals, and Laboratories 410 IAC 1-2.3 Effective October 11, 2000

http://www.in.gov/isdh/publications/comm dis rule.pdf